REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the above amendments and following remarks, which place the application into condition for allowance.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

The instant amendment is being submitted following receipt of a Notice of Noncompliant Amendment dated October 15, 2007. In the notice it was noted that withdrawn claims 1-12 and 31-33 as filed in the amendment after final rejection dated September 17, 2007 were missing from the recitation of claims. Pursuant to the Notice of Noncompliant Amendment as the preceding amendment was an after final rejection, the entire corrected amendment is resubmitted.

Claims 1-33 are pending in this application. Claims 1-12 and 31-33 have been withdrawn from consideration by a previous amendment. Claims 13-30 are rejected in the Office Action mailed on June 29, 2007. By this Amendment, claims 13, 19, and 25 are amended as detailed above. Support for these amendments can be found throughout the Specification as originally filed, published as U.S. Patent Application Publication No. 2004/0058992 ("the instant application"), for example in Figs. 9 and 12 and the corresponding detailed description for each figure found in paragraphs [0054] and [0057], respectively. It is believed that no new subject matter is added as a result of the amendments to the claims.

Initially, Applicants' attorneys would like to thank the Examiner for withdrawing the objection to claim 30, previously rejected under 35 U.S.C. § 112, first paragraph, and claims 13-30 under § 112, second paragraph based on the arguments presented in the response to the previous Office Action.

II. THE REJECTIONS UNDER 35 U.S.C. § 112

On page 3 of the Office Action, claims 13-30 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserts that claims 13 and 25, which were previously amended to recite "compress affixed to said inflatable elastic pad" is not supported in the specification. On page 4 of the Office Action, claims 13-30 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office Action indicates that claims 13 and 25 do not describe where the compress is located in the device in relation to the mask and inflatable pad. Additionally, previously amended claim 19 is rejected for allegedly failing to find support for "manual pump" in the Specification.

As to the § 112, first paragraph rejections, amended claim 13, as outlined above, recites:

> A device comprising a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth, an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad, said compress comprising a revulsive or cress having an active ingredient, wherein the device promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person in need thereof.

(Emphasis added).

Similarly, amended claim 25, as outlined above, recites:

> A method of treating sinusitis comprising the step of securing a device to a person's head, the device comprising a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth, an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad, said compress comprising a revulsive or cress having an active ingredient, wherein the device promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person in need thereof.

(Emphasis added). Paragraph [0057] of the instant application recites, *inter alia*, that a first membrane is attached to a second membrane, forming a compression chamber. Further, the first membrane is affixed to a facial mask and "[c]ompress (40) ... is subsequently fitted adjacent to second membrane." Applicants' attorneys respectfully submit that instant claims 13 and 25, as currently amended, adequately track the language found in the Specification and find support in at least paragraph [0057] to provide an adequate correlation between the position of the mask and the inflatable pad to the compress. Additionally, originally filed Fig. 12, and the associated detailed description found in at least paragraphs [0054] and [0057] of the instant application, clearly show and describe the relationship between the position of the mask, the inflatable pad comprising a first membrane and a second membrane, and the compress. Thus, Applicants' attorneys respectfully submit that the relationship between the compress and the mask and inflatable pad is clearly defined. Withdrawal of the § 112, first paragraph rejections of claims 13 and 25 is therefore respectfully requested.

Currently amended claim 19, as listed above, recites a "rubber pump." The instant application describes, in at least paragraphs [0054], a rubber pump attached to a tube and inserted between first and second membranes to pump air into the compression chamber. Applicants' attorneys respectfully submit that currently amended claim 19 now has adequate support in the Specification and accordingly respectfully request that the objection based on § 112, first paragraph, be withdrawn.

III. THE REJECTIONS UNDER 35 U.S.C. § 103(a)

On page 6 of the Office Action, the Examiner rejects claims 13, 15-25, and 27-30 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 2,262,711 to Ludwin

("Ludwin") in view of U.S. Patent No. 4,193,401 to Marinello ("Marinello"). The rejections are traversed for at least the following reasons.

As recited in revised independent claim 13, the instant invention is directed to a facial mask comprising, *inter alia*, a compress containing a revulsive or a cress, fitted adjacent to an inflatable pad, "wherein the device promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person in need thereof." (Emphasis added.) As disclosed at least in paragraph [0010] of the instant application, the active ingredient of the present invention penetrates the skin of the wearer to promote absorption of the active ingredient to bones underlying the mucous membranes in the sinuses. As further recited in revised independent claim 13 and in paragraph [0035] of the instant application, the mask of the instant invention allows the nostrils and mouth of the wearer to freely accommodate normal respiratory functions. Figures 1 and 2, illustrating the first and second embodiments of the instant invention, indicate that the areas corresponding to the wearer's mouth and nose are open for free communication with the environment beyond the mask. Further, paragraph [0047] of the instant application provides a detailed description of Figures 1 and 2 and recites that "in both cases (i.e. embodiment 1 and embodiment 2) a person's nostrils and mouth are free to accommodate respiratory functions." Based on the instant disclosure, one of ordinary skill in the art would understand that the instant invention is not configured to introduce any substance to the respiratory system.

In contrast, Ludwin relates to a "medicament spraying apparatus" (Ludwin, column 4, line 19) comprising, *inter alia*, a mask "adapted to fit over the nose and mouth" (Id. column 2, lines 1-2), a nebulizer containing the medicament, a motor driven rotary compressor, and "suitable tubing connecting the compressor…to said nebulizer, and the nebulizer to said mask."

(Id. column 2, lines 2-9). As noted on page 7 of the Office Action, the medicaments may be contained in a sponge member. A further review of the cited portion of Ludwin, specifically column 3, lines 21-27, indicates an embodiment in which the sponge member is contained in a glass tube element of an injector. The injector is connected by a tube to the compressor at a lower end, and the upper end fitted with injectors "which may be inserted in the nostrils." From this description, one skilled in the art would understand that the sponge member is not a component of the mask, nor does the embodiment described allow unobstructed respiratory functions of the nostrils. Thus, Ludwin's invention makes the nose and/or mouth of the wearer unavailable for normal respiratory function while introducing volatized medicaments to the respiratory system of the wearer. Ludwin fails to teach or suggest the absorption of any medicament to bones underlying mucous membranes in the sinuses of a person in need thereof.

Marinello fails to cure the deficiencies of Ludwin. Marinello is directed to an apparatus applicable to the external part of the orbital cavity to introduce medicaments for the cure of internal injuries, wounds, or inflammation to the ocular organs and the central nervous system. See e.g. Marinello, col. 3, lines 35-43. Marinello fails to teach or suggest an apparatus that would be appropriate or effective for the introduction of medicaments to any other tissue. Specifically, there is no suggestion that such an apparatus would be successful in delivering active ingredients through mucous membranes to the underlying bones in the sinuses. As presently understood, Marinello is directed specifically to the treatment of the ocular organs and the central nervous system which does not suggest absorption into bone.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings either in the references themselves or in the general knowledge available to

one of ordinary skill in the art; second, there must be a reasonable expectation of success; third, the prior art reference or references must teach or suggest all the claim limitations. *M.P.E.P.* § 2143; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989); *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986); and *In re Royka*, 490 F.2d 981 (CCPA 1974). Therefore, because the combination of Ludwin and Marinello at least fails to teach, disclose or suggest all of the instant claim limitations, specifically the absorption of the active ingredients to bones underlying mucous membranes in a sinus of the wearer, the Section 103 rejections must fail as a matter of law. Accordingly, Applicants' attorneys respectfully request that the Section 103 rejections be withdrawn.

For at least the foregoing reasons, it is believed that revised independent claim 13 patentably distinguish over the relied upon portions of Ludwin and Marinello, either alone or in combination, and is therefore allowable. Revised independent claim 25 is similar or somewhat similar in scope to revised independent claim 13 and is therefore allowable for similar or somewhat similar reasons to those for claim 13. Further, claims 14-24, which depend from claim 13, and claims 26-30 which depend from claim 25, are allowable as well.

Statements appearing above with respect to the disclosures in the cited references represent the present opinions of the Applicants' undersigned attorney and, in the event that the Examiner disagrees with any such opinions, it is respectfully requested that the Examiner specifically indicate those portions of the respective reference providing the basis for a contrary view.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are patentable over the prior art, and an early and favorable consideration thereof is solicited.

Please charge any fees incurred by reason of this response and not paid herewith to Deposit Account No. 50-0320.

Respectfully submitted,
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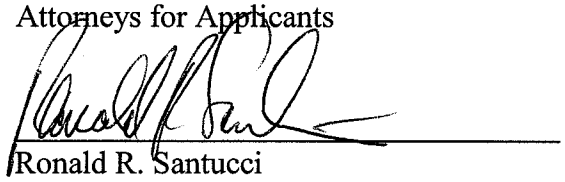
By: 

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